



## EEC-Safety Data Sheet

\*\*\*\* noch wie deutsches machen\*\*\*\*

**Product: Temporary Crowns and Shells**

**01. Material**  
Aluminium / Tin

**02. Composition**

**Aluminium:**

Al 99,5%

Balance 0,5 % (max Si 0,25 / Fe 0,40 / Cu 0,05 / Mn 0,05 / Mg 0,05 / Zn 0,07 / Ti 0,05)

**Tin:**

Sn 98,00%

Sb 2,00%

**03. Warning informations**

Possible Danger to human being and environment are none known, provided appropriate storage and handing.

**Side effects:**

Up to now, concerning this product no unwanted side effects became known to us. Unwanted side effects are very rarely to be expected by appropriate treatment and application. However in general immune reactions (such as for example allergies) or local irritations can be never entirely excluded. We kindly ask you to inform us if unwanted side effects become known to you.

**Contra-indications/ Interactions:**

In case of hypersensitivity of the patient to one of the components, this medical product is to be used under the latitude and the medical supervision of the attending dentist. You can get further information about the composition of this medical product in the tables. The dentist has to consider, while using this medical product, the known cross-reactions or interactions of the medical product with other medical products or materials, already applicated in the mouth. For patients with metallic dental fillings (e.g. Amalgam, Gold) in their dentures, we recommend to use Protect Crowns REF 480X.. with passivated, gold coloured oxide layer.

**04. First-Aid-Measures**

Usual measurements adequate to the situation, no special measurements



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#### 05. Measures for fire extinction

Product is not flammable. Surrounded fire can be extinguished by appropriate means.

#### 06. Measures in case of unintentional destruction

No special measures necessary

#### 07. Storage

In dry condition

#### 08. Shelf life

When observing these conditions the product has unlimited shelf life.

#### 09. Hygiene Measures and Sterilisation Methods

Sterilise instruments by autoclave or hot air before initial use

#### 10. Physical and chemical Properties

Condition	solid
Colour	metallic
Odour	none
Change of condition	Melting point
Flash point	not applicable
Density	not applicable
pH-Value	not applicable
Viscosity	not applicable
Water-soluble	insoluble

#### 11. Stability and Reactivity

Dangerous reactions are unknown. Stable and not reactive under appropriate storage.

#### 12. Information on Toxicology

Toxic effects are unknown.

Tin and Aluminium tested acc. ISO 10993 (Biological evaluation of medical devices):

- no local reaction of tissue.
- no indication of sensitizing properties
- no cytotoxic reaction in L929 mouse fibroblasts-test



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**13. Information on Ecology**

Damaging effects are unknown

**14. Information about disposal**

Can be removed together with common trash inline with public regulations, preferable with scrab metal

**15. Transport Information**

No special requirements with respect to transport regulations

**16. Regulations**

Labeling according to Directive EEC 93/42

**17. Others**

The above mentioned information are based on our latest knowledge and describes the product as for safety aspects without assuring technical properties and features.

Existing law and regulations must be observed by the user under its own responsibility.

According to the European directive EEC 93/42, these medical products may only be used by the dentist himself or by instructed, special qualified staff.

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